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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	ALEX-P01-055	3521
28120 7590 12/28/2006 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/28/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,591	BOWDISH ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	<i>WLF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,23,24,26-37,73,74 and 85-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,23,24,26-37,73,74 and 85-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of the papers filed 8/21/2006 in which claims 1-6, 23-24, 26-36, 73-74, 85-90 and 92-95 were amended, and claims 97-104 were added. Claims 1-6, 23-24, 26-37, 73-74 and 85-104 are pending and under examination in the instant Office action.

Any rejection made in the previous Office action not recited herein is hereby withdrawn.

Drawings

The amendment to the specification to include the reference character present in Figure 7 is remedial to overcome the objection to the drawings set forth in the previous Office action. The objection to the drawings is withdrawn.

Claim Objections

Applicant's amendment to the claims is remedial to overcome the objection to claims 23, 28-36, 85, 88-89 and 92-94. The objection to the claims is withdrawn.

Art Unit: 1636

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 23, 33-36, 85, 92 & 97-100, and therefore dependent claims 2-6, 24, 26-32, 37, 73-74, 86-91, 93-96 & 101-104, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. **Any new rejections recited herein were necessitated by Applicant's amendment.**

Claims 1, 23, 33-36, 85 and 92 recite primer and collar sequences which are "capable of annealing during a polymerase reaction" to at least a portion of a polypeptide-encoding portion of a nucleic acid. Claims 1, 23, 33-36, 85 and 92 are vague and indefinite in that the metes and bounds of such a primer sequence or collar sequence are unclear. Does Applicant intend to encompass only those primer and/or collar sequences which anneal to a complementary nucleic acid under stringent polymerase reaction conditions or within a particular temperature range or salt concentration, or does Applicant intend a much broader interpretation, including nucleic acid

Art Unit: 1636

sequences which may only anneal to one or two bases - even within a polymerase reaction?

Claim s 97-100 recite the limitation "said polymerase" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Response to Arguments

Applicant argues that the phrase "capable of annealing during a polymerase reaction" is a term of art and that one of ordinary skill in the art at the time of filing would have known "the standard conditions usable for a successful polymerase reaction and that a successful polymerase reaction required more than a 1 nucleotide match for annealing to occur" (see page 11, 2nd full paragraph of the remarks filed 8/21/2006).

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. Examiner agrees that one of ordinary skill in the art would know standard conditions usable for a successful polymerase reaction; however, Applicant has claimed nucleic acid sequences "capable of annealing during a polymerase reaction" and one of ordinary skill in the art would also know that annealing of nucleic acids requires no more one nucleotide from each nucleic acid strand being annealed. Furthermore, while the terms "anneal" and "polymerase reaction"

Art Unit: 1636

may be terms of art, Examiner does not agree that the phrase "capable of annealing during a polymerase reaction" is a term of art.

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 23-24, 26-37, 73-74 and 85-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record and extended to new claims 97-104.**

Response to Arguments

Applicant argues that the claimed subject matter as amended is described sufficiently in the specification to indicate that Applicant was in possession of the invention at the time of

Art Unit: 1636

filing. Applicant asserts that the specification satisfies The Written Description Guidelines for the Examination of Patent Applications. In support of this assertion, Applicant points to exemplary passages within the specification such as that from page 6, lines 18-22 which discloses that "[t]he downstream primer and upstream collar sequence should be of sufficient length to support specific and stable hybridization" and that "[t]he annealing sequences may individually contain from about 10 nucleotides to about 50 or more nucleotides in length" (see also page 12, last paragraph of the remarks filed 8/21/2006). Applicant further argues that the inventive portion of the subject matter is disclosed and any additional variability within the genus arises due to additional elements that are not part of the inventor's contribution and as such, the written description cannot be deemed defective. Applicant further argues that one of ordinary skill in the art would know that the inventive portion of the subject matter is the technical feature of the primer sequence and the collar sequence. Applicant further argues that it is routine to determine the structure of a suitable annealing sequence for any selected location along a known mRNA once the sequence is ascertained.

Applicant's arguments have been carefully considered but are respectfully found unpersuasive for the following reasons.

Art Unit: 1636

Applicant's assertion that the specification satisfies The Written Description Guidelines for the Examination of Patent Applications is not persuasive because general teachings regarding the length of annealing sequences and the disclosure of a few specific primer and collar sequences such as SEQ ID NOs: 3-4 and 7-8, in context of the claimed subject matter, do not amount to sufficient distinguishing identifying characteristics of the genus which, in the instant case, comprises ANY primer or ANY collar sequence which can anneal during a polymerase reaction to ANY portion (however long or short) of any polypeptide-encoding portion of a nucleic acid. Limitation of such sequences to those which are 10 or 15 nucleotides in length and/or to those capable of annealing "during a polymerase reaction" does not render the genus significantly narrower as any portion of the sequence must, as before, simply be capable of annealing to ANY portion of any polypeptide-encoding portion of any nucleic acid as long as the polypeptide-encoding portions to which the primer anneals are at least 20 nucleotides apart. Furthermore, the teachings of the specification are not predictive of any other sequences capable of annealing to different portions of a coding region of a nucleic acid encoding an antibody or a portion of an antibody, such that the vector can be used to clone a nucleic acid of

Art Unit: 1636

interest. Thus it is impossible to extrapolate from the example(s) described in the specification those nucleic acid molecules that would necessarily meet the structural/functional characteristics of the rejected claims. Applicant's argument that one of ordinary skill in the art would know that the inventive portion of the subject matter at hand is the technical feature of the primer sequence and the collar sequence in fact raises the standard for written description in the instant case insofar as such technical features (sequences) are the Applicant's invention. It is therefore more important that Applicant teach one of ordinary skill in the art how to both make and use the claimed inventive features. Finally, Examiner agrees with Applicant insofar as it is routine to determine the structure of an annealing sequence for any selected location along a known mRNA once the sequence is ascertained, but Applicant has not claimed such a process. Applicant has claimed ANY primer or ANY collar sequence capable of annealing during a polymerase reaction to ANY portion of a polypeptide encoding portion of a nucleic acid as long as the portions are separated by at least 20 nucleotides in length.

Claims 1-6, 23-24, 26-32, 73-74 and 85-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with

Art Unit: 1636

the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection. This is a new rejection necessitated by Applicant's amendment.**

The specification as originally filed does not provide support for the invention as now claimed: "a primer sequence of at least 10 nucleotides" or "a collar sequence of at least 10 nucleotides" (claims 1-6, 23-24, 26-32, 73-74 and 85-100) or "a primer sequence of at least 15 nucleotides" or "a collar sequence of at least 15 nucleotides" (claim 101-104). The specification does not provide sufficient blazemarks nor direction for the instant primer/collar sequence lengths encompassed by the above-mentioned limitation, as currently recited. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 23-24, 26-32, 37, 73-74, 97-98 and 101-102 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (*PNAS* 80:1194-1198, 1983; of record). **This rejection is maintained for reasons of record and extended to new claims 97-98 and 101-102.**

Claims 23-24, 26-32, 37, 74, 85-96, 99-100 and 103-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohno et al (*Gene* 188:175-181, 1997; of record). **This rejection is maintained for reasons of record and extended to new claims 99-100 and 103-104.**

Response to Arguments

Applicant traverses Examiner's claim construction of the term "portion" and argues that the second portion of the polypeptide-encoding portion of the nucleic acid taught by Young

Art Unit: 1636

et al is not separated by at least 20 nucleotides from the first portion of the polypeptide-encoding portion of the nucleic acid. In fact, Applicant argues, the "first portion" and the "second portion" constitute the complete lacZ coding sequence with no gap/separation between these two portions. This, Applicant argues, is contrary to the claims, which Applicant argues require that the second portion of the polypeptide-encoding portion of the nucleic acid be separated by at least 20 nucleotides from the first portion of the polypeptide-encoding portion of the nucleic acid. Applicant further argues that even assuming that claims were to be given their broadest reasonable interpretation to include portions which are only a single nucleotide in length, Young et al fail to anticipate claims 23, 85 and 92 because Young et al do not teach or suggest the coding sequence of the mRNA encoding an antibody, the framework region associated with an antibody or the constant region associated with any antibody as recited.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. Contrary to Applicant's assertion, the claims do NOT require that the first portion and the second portion *of the polypeptide-encoding nucleic acid* be separated by at least 20 nucleotides; the claims require only that the primer and collar sequences, each of at least 10

Art Unit: 1636

nucleotides in length, *be capable of annealing to* portions of a first and second portion of a polypeptide-encoding portion of a nucleic acid which are separated by 20 nucleotides. As such, the Young et al reference need not explicitly disclose such portions as portions which are coding sequences of an mRNA encoding an antibody, the framework region associated with an antibody or the constant regions associated with an antibody in order to meet all the claim limitations.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1636

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

Art Unit: 1636

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For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

December 21, 2006


NANCY VOGEL
PRIMARY EXAMINER